In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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M.G., parent and natural guardian, of J.M.G.,	*	PUBLISHED
Petitioner,	*	No. 17-743V
v.	*	Special Master Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal Decision; Failure to Prosecute; Insufficient Proof; Entitlement; Motion to Recuse; Motion to Vacate or Delay Deadlines.
Respondent.	*	

M.G., pro se, Los Angeles, CA, for petitioner.
Colleen Hartley, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. INTRODUCTION

On June 6, 2017, M.G. ("petitioner"), parent and natural guardian of J.M.G., filed a pro se petition for compensation in the National Vaccine Injury Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleged that J.M.G. experienced a "severe adverse reaction" as the result of diphtheria-tetanus-acellular-pertussis ("DTaP"),

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

hepatitis B, Rotavirus, haemophilus influenzae type b ("Hib"), pneumococcal conjugate ("PCV 13"), and inactivated polio ("IPV") vaccinations administered on May 13, 2014 and July 16, 2014. Amended ("Am.") Petition at 1 (ECF No. 34).

Based on all the reasons set forth below and in the Show Cause Order dated May 28, 2021, and for failure to comply with the Show Cause Order, as well as failure to comply with subsequent orders, the undersigned **DISMISSES** this case for failure to prosecute and insufficient proof. In doing so, the undersigned **GRANTS** respondent's motion for an order to show cause and to dismiss the case. Respondent's Motion ("Resp. Mot.") for Order to Show Cause, filed Mar. 4, 2022 (ECF No. 150).

Additionally, based on all the reasons set forth below and in the Order Denying Motion to Recuse and Granting Motion to Vacate or Delay Deadlines dated December 23, 2021, petitioner's second Motion for Recusal and second Motion to Vacate or Delay Deadlines are also **DENIED**. See Petitioner's ("Pet.") Second Mot. for Recusal, filed Feb. 17, 2022 (ECF No. 146); Pet. Second Mot. to Vacate or Delay, Deadline to Produce Medical Records and Expert Report, Currently Set at February 22, 2022 ("Pet. Second Mot. to Vacate"), filed Feb. 18, 2022 (ECF No. 148).

Moreover, the undersigned finds that petitioner has failed to prove by preponderant evidence that the vaccinations administered to J.M.G. on May 13, 2014 and July 16, 2014, caused any severe adverse reaction based on an Althen causation analysis. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005). Thus, the undersigned finds petitioner is not entitled to compensation.

II. PROCEDURAL HISTORY

On June 6, 2017, petitioner filed his claim pro se alleging that J.M.G. suffered adverse effects of vaccinations, including "extremely rapid head growth" and global developmental delay as the result of "governmental recommended vaccination." Petition at 1-2 (ECF No. 1). Petitioner filed medical records with his petition, including proof of vaccination. Petitioner's Exhibits ("Pet. Exs.") 1-4.

Petitioner filed additional medical records on September 27, 2017, including a letter from Cathy Buckley, Ph.D. Medical Records (ECF No. 10). On November 16, 2017, the special master assigned to the case scheduled a status conference regarding petitioner's compliance with court deadlines to file all requested medical records. See Order dated Nov. 17, 2021 (ECF No. 14). The special master asked petitioner to file outstanding medical records by the end of December 2017. Transcript ("Tr.") 9 (ECF No. 16).

On December 14, 2017, the case was reassigned to the undersigned. Order Reassigning Case dated Dec. 14, 2017 (ECF No. 18). Petitioner filed medical records on January 18, 2018. Medical Records (ECF No. 21). On February 9, 2018, petitioner filed a motion to substitute Mr. Andrew Downing as attorney of record. Mot. to Substitute Attorney, filed Feb. 9, 2018 (ECF No. 23).

Respondent filed respondent's Rule 4(c) Report on February 20, 2018, arguing against compensation. Respondent's Report ("Resp. Rept.") at 2. Petitioner filed a statement, amended petition, medical records, and a Statement of Completion in March and May 2018. Pet. Exs. 6-9; Statement of Completion, filed May 23, 2018 (ECF No. 31); Am. Petition. On August 17, 2018, petitioner filed an expert report from Dr. Karen Harum. Pet. Exs. 10-15. Respondent filed two responsive expert reports from Dr. Peter Bingham and Dr. Joseph Blattman in November 2018 and April 2019. Resp. Exs. A-D.

On March 26, 2019, petitioner filed a motion to withdraw Mr. Downing as attorney of record. Mot. to Withdraw Attorney, filed Mar. 26, 2019 (ECF No. 45). Petitioner then filed a motion to substitute Mr. David Murphy as attorney of record on April 10, 2019. Mot. to Substitute Attorney, filed Apr. 10, 2019 (ECF No. 51).

The undersigned held a Rule 5 conference on May 23, 2019. Prior to sharing her preliminary evaluation, the undersigned obtained consent of the parties. Rule 5 Order dated May 28, 2019 (ECF No. 57). During the Rule 5 conference, the undersigned reviewed petitioner's experts' reports and noted that Dr. Buckley's and Dr. Harum's opinions were conclusory and lacking in foundational evidence. Id. at 1-2. The undersigned found respondent's experts' conclusions were persuasive and supported by evidence in the medical records and medical literature. Id. at 2-3. The undersigned concluded that petitioner was not entitled to compensation and that going forward, the case lacked reasonable basis. Id. at 2. The undersigned ordered petitioner to file a status report indicating how he wished to proceed. Id.

Petitioner subsequently filed a motion for extension of time until July 26, 2019, to file the status report, and the motion was granted. Order dated Aug. 5, 2019 (ECF No.67). From July to October 2019, petitioner filed supplemental expert reports from Drs. Buckley and Harum and a motion for reconsideration with an affidavit and medical records. Pet. Exs. 16-24; Pet. Mot. to Reconsider Rule 5 Order ("Pet. Mot. to Reconsider"), filed Oct. 24, 2019 (ECF No. 72); Pet. Memorandum in Support of Mot. to Reconsider ("Pet. Memo."), filed Oct. 24, 2019 (ECF No. 73). On December 11 and 12, 2019, respondent filed a supplemental responsive expert report and a response to petitioner's motion, requesting the undersigned deny petitioner's motion for reconsideration. Resp. Ex. E; Resp. Response to Pet. Mot. to Reconsider, filed Dec. 12, 2019 (ECF No. 76). On January 15, 2020, the undersigned denied petitioner's motion for reconsideration of her Rule 5 Order. Order Denying Pet. Mot. for Reconsideration dated Jan. 15, 2020 (ECF No. 77). The undersigned again made a preliminary finding that petitioner was not entitled to compensation. Id. at 3. Petitioner was given another 30 days to file a motion to dismiss or a motion for a ruling on the record. Id.

On February 14, 2020, petitioner filed a response to the order denying petitioner's motion for reconsideration, requesting a status conference, and objecting to resolving the case by a ruling on the record. Pet. Response to Order Denying Pet. Mot. for Reconsideration, filed Feb. 14, 2020 (ECF No. 78). Petitioner also filed a motion for order to reinstate eligibility for funding. Id. The undersigned held a status conference on March 5, 2020, attended by petitioner and his counsel of record, in which she stated,

> Here, petitioner does not present a 'sound and reliable' medical theory. There is no recognized theory or view in the scientific community that vaccines are causally associated with hydrocephalus or developmental delay. The theories presented by Dr. Buckley and Dr. Harum are not 'sound and reliable,' nor persuasive for all the reasons set forth in the Boatmon[3] decision.
>
> However, petitioner does not think he has been afforded a full and fair opportunity to present his case, and in light of that, the undersigned must consider whether she has given him sufficient opportunity to develop his case through expert opinions. . . .
>
> Because petitioner does not feel the undersigned's Order was fair, and because he already paid $2,000.00 for an expert, the undersigned decided to grant petitioner's motion for the limited purpose of obtaining an expert report detailing a sound and reliable medical theory which appropriately addresses the Althen requirements. The undersigned will not withdraw her Rule 5 Order and will not agree to hold a hearing absent a compelling and appropriate expert report.

Order dated Mar. 9, 2020, at 1-2 (ECF No. 79). Thus, the undersigned afforded the petitioner another opportunity to pursue an expert report and file updated medical records in sixty days. Id. at 3.

However, in the past two years petitioner has failed to file an expert report or updated medical records. On April 10, 2020, petitioner filed his first motion for extension of time to file medical records and an expert report. Pet. Mot. for Extension of Time, filed Apr. 10, 2020 (ECF No. 80). Petitioner's motion was granted, and the deadline was extended to June 12, 2020. Order dated Apr. 13, 2020 (ECF No. 81). Subsequently, petitioner filed a motion to withdraw attorney Mr. Murphy as counsel of record and continue the case pro se on June 4, 2020. Pet. Mot. to Withdraw Attorney, filed June 4, 2020 (ECF No. 85). Petitioner's motion was granted. Order Granting Pet. Mot. to Withdraw Attorney dated June 5, 2020 (ECF No. 86).

Subsequently, the undersigned granted petitioner's motions for extension of time on July 30, 2020, October 5, 2020, December 3, 2020, January 27, 2021, and March 29, 2021. Order dated July 30, 2020 (ECF No. 105); Order dated Oct. 5, 2020 (ECF No. 123); Order dated Dec. 3, 2020 (ECF No. 129); Order dated Jan. 27, 2021 (ECF No. 132); Order dated Mar. 29, 2021 (ECF No. 136). From July 2020 to March 2021, the only records petitioner filed were J.M.G.'s 2020 school records. School Records, filed Mar. 29, 2021 (ECF No. 133). Petitioner did not file updated medical records from J.M.G.'s pediatric neurologist. Nor did petitioner file an expert report.

On April 8, 2021, respondent e-mailed the undersigned's law clerk requesting a status conference. Order dated Apr. 22, 2021, at 2 (ECF No. 138). Petitioner was copied on the email. Id. On April 14, 15, and 19, 2021, the undersigned's law clerk e-mailed both parties providing dates and times to schedule a status conference. Id. On April 19, 2021, petitioner replied that his

[3] Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

father recently passed away and he was unable to attend a status conference at this time. Id. It is the undersigned's general practice to hold a status conference when requested by either party. However, under the circumstances a status conference was not scheduled, due to petitioner's unavailability. Petitioner's deadline to file J.M.G.'s updated medical records and expert report was extended to May 28, 2021. Id.

On May 27, 2021, petitioner filed his seventh motion for extension of time to file updated medical records and an expert report. Pet. Mot. for Extension of Time, filed May 27, 2021 (ECF No. 139). In his motion, petitioner stated,

> [p]etitioner's family has experienced the recent death of [p]etitioner's Father on April 11, 2021. The [p]etitioner's Father's passing comes less than 2 months from the passing for [p]etitioner's Sister, who passed away on February 19, 2021. Both members of the family were extremely cherished and loved by the whole family unit. The [p]etitioner's Father was a particularly important member of the general family unit. His loss to the family has caused great stress and anxiety on the entire family.

Id. Petitioner, therefore, requested until September 29, 2021, to file updated medical records and an expert report. Id. The undersigned granted the motion, but also issued an Order to Show Cause, due to the length of time that petitioner had been given to file records from the pediatric neurologist and an expert report. Order to Show Cause dated May 28, 2021 (ECF No. 140).

Thus, on May 28, 2021, the undersigned issued an Order to Show Cause stating,

> It has been over one year since petitioner was ordered to file medical records and an expert report. Due to the COVID-19 pandemic, the undersigned has granted numerous motions for extension of time for petitioner to file J.M.G.'s medical records and an expert report. Accordingly, the undersigned shall grant petitioner's seventh request for additional time. The undersigned expresses her deepest condolences for the tragic losses to petitioner and his family. Going forward, however, no further extensions shall be granted. Failure to file the requested medical records and an expert report will result in the dismissal of the petition for failure to prosecute. Therefore, the undersigned GRANTS petitioner's 124-day request to file medical records and an expert report. However, if the documents are not filed by September 29, 2021, the case will be dismissed.

Order to Show Cause dated May 28, 2021 (ECF No. 140).

In September 2021, petitioner did not file updated medical records or an expert report. Instead, petitioner filed a motion for recusal, requesting that the undersigned "recuse herself for demonstrating a lack of objectivity and impartiality in her conduct towards [p]etitioner." Pet. First Mot. for Recusal, filed Sept. 21, 2021, at 1 (ECF No. 141). Petitioner attached Mr. Murphy's February 14, 2020, response to the order denying petitioner's motion for reconsideration, requesting a status conference, and objecting to resolving the case by a ruling on

the record as support for his contentions that the undersigned should be recused. See id.; Pet. Response to Order Denying Pet. Mot. for Reconsideration. Petitioner also filed a motion to vacate or delay the deadline to produce medical records and an expert report. Pet. First Mot. to Vacate, filed Sept. 23, 2021 (ECF No. 143). Petitioner requested the deadline for medical records and an expert report be vacated or delayed until the motion for recusal was addressed. Id. at 1. Respondent responded to both of petitioner's motions stating, "[r]espondent takes no position on th[ese] motion[s]." Resp. Response to Pet. First Mot. for Recusal, filed Sept. 22, 2021 (ECF No. 142); Resp. Response to Pet. First Mot. to Vacate, filed Sept. 24, 2021 (ECF No. 144).

The undesigned issued an Order on December 23, 2021, denying petitioner's motion for recusal and granting petitioner's motion to vacate the deadlines. Order Denying Pet. First Mot. for Recusal and Granting Pet. First Mot. to Vacate dated Dec. 23, 2021 (ECF No. 145). The undersigned then extended petitioner's deadline to file updated medical records and an expert report by sixty days or until February 22, 2022. Id.

Petitioner again failed to file updated medical records and an expert report by the court-imposed deadline, and instead, filed a second motion for recusal and second motion to vacate on February 17 and 18, 2022. Pet. Second Mot. for Recusal; Pet. Second Mot. to Vacate. The present motions for recusal and to vacate restate the allegations raised previously in petitioner's first motions for recusal and to vacate. Petitioner again attached Mr. Murphy's February 14, 2020 response to his recusal motion. Pet. Second Mot. for Recusal. On February 18, 2022, respondent filed a response to petitioner's motion for recusal stating, "the subject motion does not involve respondent. Accordingly, respondent takes no position on the same." Resp. Response to Pet. Second Mot. for Recusal, filed Feb. 18, 2022 (ECF No. 147). Respondent filed a response to petitioner's second motion to vacate on March 4, 2022. Resp. Response to Pet. Second Mot. to Vacate, filed Mar. 4, 2022 (ECF No. 149). Respondent stated, "[p]etitioner did not contact respondent regarding the subject motion. Respondent objects to the motion." Id. at 1. Respondent argued that Covid-19 related issues and personal hardships "have not stalled [other] cases for two calendar years." Id. at 2. Respondent stated, "[a]ccordingly, given that petitioner has had two years to comply with the special master's initial order, petitioner's motion for extension should be denied." Id.

On March 4, 2022, respondent also filed a motion for an order to show cause. Resp. Mot. for Order to Show Cause. Respondent stated, "[t]o date, petitioner has failed to file an expert report or updated medical records after being afforded two years to do so. This case should be dismissed. Accordingly, respondent requests that this Court either dismiss this matter for failure to prosecute pursuant to the December 23, 2021 Order, or issue a renewed Order to Show Cause." Id. at 2.

On March 9, 2022, petitioner filed responses to respondent's objection to petitioner's second motion to vacate deadlines and respondent's motion for an order to show cause. Pet. Answer to Resp. Objection to Pet. Second Mot. to Vacate or Delay Deadline ("Pet. Reply"), filed Mar. 9, 2022 (ECF No. 151); Pet. Response to Resp. Mot. for Order to Show Cause and Dismiss Case ("Pet. Response"), filed Mar. 9, 2022 (ECF No. 152). In his Reply, petitioner stated petitioner had previously made motions for extension of time without consulting respondent and

that such motions were granted. Pet. Reply at 1. In petitioner's response to respondent's motion for Order to Show Cause, petitioner stated he presented "overwhelming" evidence of the undersigned's prejudicial conduct and that respondent has "no objection" to his motion.[4] Pet. Response at 1. Petitioner stated he has "already shown cause for this case" by filing medical records and several expert reports. Id. Petitioner then repeated assertions made in previous motions for recusal. Id. at 2. Petitioner once again attached his prior attorney's February 14, 2020 response to support his allegations. Id. at 5-15.

This matter is ripe for adjudication.

III. RELEVANT FACTUAL SUMMARY

A. Medical Records

[redacted]. Medical Records at 7 (ECF No. 10). The medical records do not indicate there were any prenatal problems or problems during labor. At birth, J.M.G.'s head circumference was 36 cm, above the 90th percentile. Id. at 27. His length was also above the 90th percentile and his weight was just below the 90th percentile. Id.

On May 13, 2014, J.M.G. received his two-month vaccinations, including his first hepatitis B, DTaP, Rotavirus, Hib, PCV 13, and IPV vaccinations. Medical Records at 45 (ECF No. 10). At this checkup, J.M.G.'s head circumference was in the 75th percentile.[5] Id. at 71. No adverse reaction to the vaccines was noted in J.M.G.'s medical records.

At his four-month well baby checkup, J.M.G. received his second hepatitis B, DTaP, Rotavirus, Hib, PCV 13, and IPV vaccinations on July 14, 2014. Id. J.M.G.'s head circumference was 46 cm, well above the 95th percentile. Id. at 71. Again, there was no adverse reaction noted to the vaccines.

Dr. Vicki Schiller, radiologist, performed a cranial sonogram on July 22, 2014. Pet. Ex. 8 at 1. Dr. Schiller's findings were "[u]ltrasound is performed using the anterior fontanelle.[6] There is an extra-axial fluid collection. The ventricles are prominent in size. There is no

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[4] Respondent's response to petitioner's second motion was "respondent takes no position," on petitioner's motion. Resp. Response to Pet. Second Mot. for Recusal at 1.

[5] J.M.G. had a head circumference above the 90th percentile at birth, but at his two-month visit, his head circumference was in the 75th percentile. Medical Records at (ECF No. 10). The next visit, at four months, J.M.G.'s head circumference was above 95th percentile. Id. The numbers suggest that the second measurement of 75th percentile may not be accurate, as it is quite different that the other measurements.

[6] Fontanelles are the "membrane-covered spaces, or soft spots, remaining at the incomplete angles of the parietal and adjacent bones, until ossification of the skull is completed." Fonticuli Cranii, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=76894 (last visited Mar. 8, 2022).

evidence of porencephaly.[7] Conclusion: Extra-axial fluid collection. Further imaging with MRI suggested." Id. at 2.

A neurologic evaluation was conducted by Dr. Harriet Cokely on July 30, 2014, due to concerns of escalating head circumference. Medical Records at 71 (ECF No. 10). Dr. Cokely noted that J.M.G.'s "head circumference at 1 and 2 months was the 90th and 75th percentile, but at the four months, it was 46 cm well above the 95th percentile." Id. Otherwise, J.M.G. was "developing nicely." Id. Dr. Cokely reviewed J.M.G.'s family history and found that J.M.G.'s parents' head circumferences also measured in, and above, the 98th percentile. Id. Additionally, J.M.G.'s mother stated she had had a syncopal episode in her childhood and imagining studies showed increased space between her brain and the skull, but no other problems. Id. Dr. Cokely stated, "likely, this is a genetic condition based upon mom's history and he has just delayed absorption of spinal fluid in the subarachnoid space." Id. at 72. Dr. Cokely did not document that J.M.G. had any adverse reaction to his prior vaccinations.

J.M.G. had a follow up ultrasound on August 20, 2014. Pet. Ex. 8 at 29. Dr. Bruce Yawitz, a radiologist, found "[t]here is prominent [cerebral spinal fluid] at the high convexities, not felt to be normal. There is no ventricular enlargement to suggest hydrocephalus. No gross gyriform abnormalities are seen. I believe there is a normal corpus callosum. There are no porencephalic changes." Id. at 30. Dr. Yawitz's impression was "[stable] abnormal enlargement of the [cerebral spinal fluid] spaces. No hydrocephalus. MRI recommended." Id.

On September 3, 2014, an additional head ultrasound was performed by Dr. Srinivas Peddi, a radiologist. Pet. Ex. 8 at 56-57. Dr. Peddi noted, "[t]he ventricular system is within normal limits with no evidence of subependymal or intraventricular hemorrhage. No intraparenchymal hemorrhage or periventricular leukomalacia is appreciated. No mass-effect is seen. The extra-axial spaces are prominent, unchanged from prior exam." Id. at 57. An incompletely evaluated "5 mm hypoechoic focus [was] noted along the posterior aspect of the right lateral ventricle." Id. The impression was "[t]here is prominence of the extra-axial spaces, unchanged from prior exams. Findings may be seen in the setting of benign enlargement of the subarachnoid spaces in infancy (also referred to as benign external hydrocephalus). MRI may be considered for further evaluation if clinically indicated." Id.

On September 16, 2014, J.M.G. received his third Rotavirus, DTaP, Hib, PCV 13, and IPV vaccinations and his first influenza ("flu") vaccination. Medical Records at 45-46 (ECF No. 10). J.M.G. received his third hepatitis B and second flu vaccinations on October 24, 2014. Id. There is no indication in J.M.G.'s medical records to suggest that he had any adverse reaction to these vaccinations.

J.M.G. followed up with Dr. Cokely on August 25, 2014, September 8, 2014, October 7, 2014, November 7, 2014, and December 10, 2014. Medical Records at 86-92, 102 (ECF No.

[7] Porencephaly is the "presence of one or more cavities in the brain, which sometimes communicate with the arachnoid space, most often occurring in fetal life or early infancy." Porencephaly, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=40398 (last visited Mar. 8, 2022).

10). Dr. Cokely assessed J.M.G. with macrocephaly secondary to enlarged extra-axial cerebral spinal fluid space and ordered several repeat cranial ultrasounds. Id. at 87. Dr. Cokely again stated that J.M.G.'s condition may be genetic. Id. at 102. Dr. Cokely did not suggest that there was any association between J.M.G.'s vaccinations and his macrocephaly.

Multiple sonographic images of the head were obtained and compared to J.M.G.'s previous imaging on December 8, 2014. Pet. Ex. 8 at 99. The history noted J.M.G.'s head circumference was above the 95th percentile and the findings showed "[r]edemonstration of an enlarged subarachnoid space, measuring up to 11 mm on the right and 17 mm on the left which is similar to most recent comparison exam from 9/3/2014. Normal ventricular system size and morphology. No subependymal or intraventricular hemorrhage. No intraparenchymal hemorrhage." Id. Dr. Simon Gabriel's impression was "[s]table enlargement of the extra-axial subarachnoid space most consistent with physiologic subarachnoid space (SAS) enlargement (aka benign macrocephaly of infancy). Less likely considerations include diffuse cerebral atrophy. MRI of the brain without contrast is recommended if findings persist beyond 18 to 24 months of age." Id.

On January 13, 2015, Dr. Cokely reviewed J.M.G.'s imaging and stated there did not appear to be any change from the previous studies. Medical Records at 84 (ECF No. 10). After review of J.M.G.'s history and his parent's history, she concluded that "the issue with [J.M.G.] seems to be genetic." Id. On March 4, 2015, Dr. Cokely assessed J.M.G. with macrocephaly with escalating head circumference and ordered a brain MRI with and without contrast. Id. at 96.

On March 16, 2015, J.M.G. received his fourth PCV 13 vaccine. Medical Records at 70 (ECF No. 10).[8] On June 15, 2015, J.M.G. received his fourth DTaP and Hib vaccinations and first hepatitis A vaccination. Medical Records at 45 (ECF No. 10). J.M.G. received a flu vaccine on November 3, 2015. Id. at 46. No adverse reaction to any of these vaccinations was documented in the medical records.

Dr. Ali Sepahdari performed a brain MRI with and without contrast on May 28, 2015 and found "[p]rominent extra-axial [cerebral spinal fluid] density fluid without evidence for underlying cerebral parenchymal abnormality, likely representing benign extracerebral fluid collections of infancy." Medical Records at 81 (ECF No. 10).

On September 13, 2016, J.M.G. had a follow up with Dr. Cokely. Medical Records at 79 (ECF No. 10). At that visit, Dr. Cokely assessed J.M.G. with developmental delay in expressive language and motor delay. Id. He had diffuse hypotonia and macrocephaly. Id. Dr. Cokely

[8] The medical records state J.M.G. received a varicella and measles-mumps-rubella ("MMR") vaccinations on March 16, 2014. Medical Records at 45 (ECF No. 10). However, the date appears to be off by one year, as it is more likely that J.M.G. received the MMR vaccine and varicella vaccine one year later in 2015, at the time of his other vaccinations based on the routine schedule for pediatric vaccinations. See Centers for Disease Control and Prevention, Child and Adolescent Immunization Schedule, https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (last visited Mar. 24, 2022).

stated, "[a]lthough, he has some traits that are suggestive of autism, I do not think he has sufficient [traits] at this point to fulfill all the criteria." Id.

J.M.G. presented to Dr. Jeffery Bourne, his pediatrician, for a well child visit on September 16, 2016. Medical Records at 55 (ECF No. 10). J.M.G.'s head circumference was in the 100th percentile and his weight and height were in the 84th and 83rd percentile, respectively. Id. at 57-58. J.M.G. was noted to have developmental delay. Id. at 58. His parents declined some vaccines. Id.

On March 22, 2017, J.M.G. had an initial individualized education program ("IEP") assessment. Medical Records at 1 (ECF No. 21). The IEP assessment stated J.M.G. was in good general health but was nonverbal. Id. at 3. At that time, J.M.G. was receiving in-home early education language and speech services and occupational therapy. Id. at 4. Based on observations, the IEP noted that J.M.G. could not fully access the classroom core curriculum due to communication limitations and inability to follow directions. Id. Under the Fine Motor/Visual Motor/Sensory Processing section, J.M.G. was noted to have "difficulty with social participation and participation in non self-directed tasks." Id. at 5. Additionally, J.M.G.'s emotional status was found to be below average in range. Id. at 8. The IEP stated, "[p]er parents[']' ratings on the Autism Spectrum Rating Scale (ASRS), [J.M.G.] demonstrates many behavioral characteristics similar to children diagnosed with Autism Spectrum Disorder (ASD). . . . Per the Childhood Autism Rating Scale, Second Edition (CARS2-ST), [J.M.G.] presents with Severe Symptoms of Autism Spectrum Disorder." Id. Under the disability or suspected disability section, the IEP listed developmental delay, autism, and speech or language impairment and recommended speech and language therapy, occupational therapy, and infant stimulation. Id. at 9. J.M.G. was offered behavior intervention consultation, language/speech, and occupational therapy services. Id. at 31.

On March 24, 2017, J.M.G. presented to Dr. Bourne for his three-year-old well child check. Medical Records at 63 (ECF No. 10). J.M.G.'s active medical problems included macrocephaly, developmental delay, and speech developmental delay. Id. His weight was in the 91st percentile and his height was in the 64th percentile. Id. at 66. In a questionnaire reviewed and discussed with Dr. Bourne, J.M.G.'s parents indicated that they had concerns about J.M.G.'s health, but responded "no," that J.M.G. had not had any problems with shots or immunizations. Id. at 63.

From July to November 2017 the Behavioral Intervention Specialists of Los Angeles ("BISLA") evaluated J.M.G. for intellectual disability and limited expressive language. Pet. Ex. 7 at 1-2. J.M.G.'s results placed him in the extremely low range for communication, functional pre-academics, self-care, and self-direction. Id. at 3. His community use and home living scores were in the low range. Id. BISLA worked with petitioner and his family to reduce J.M.G.'s protest behavior, self-stimulatory (hand-flapping) behavior, eloping, and aggressive behaviors. Id. at 4-7.

On March 30, 2018, Dr. Bourne signed a medical exemption form, exempting J.M.G. from required immunizations based on a physical condition or medical circumstance. Pet. Ex. 9 at 1. No explanation of why the form was signed was given.

Moving forward, J.M.G.'s IEP annual review for school year 2020 stated, "[J.M.G.'s] ability to sustain his engagement with classroom lessons and work on his assignments grows continuously;" however, his "[autism] eligibility does not allow him to fully access the grade level curriculum." School Records at 3. For reading, writing, and math, J.M.G.'s teachers observed he was working toward his IEP goals, though his autism did not allow him to fully access the grade level. Id. at 4-5. The IEP assigned language/speech, behavior intervention development, occupational therapy, and behavior intervention implementation services. Id. at 33-36.

As petitioner has failed to file updated records, or records from J.M.G.'s pediatric neurologist, J.M.G.'s current condition and diagnosis are not known.

B. Petitioner's Affidavit

Petitioner executed his affidavit on October 24, 2019. Petitioner is the father of J.M.G. Pet. Ex. 6 at ¶ 1. There were no complications during pregnancy or birth. Id. at ¶ 2. On May 13, 2014, at his two-month well baby visit, J.M.G.'s head circumference measured at 39.8 cm, the 75th percentile for children his age. Id. at ¶ 3. The pediatrician stated J.M.G. was healthy and developing nicely and administered 6 different vaccinations: hepatitis B, Rotavirus, DTaP, Hib, PCV 13, and IPV. Id. Petitioner averred that between the two-month and four-month checkups, he never witnessed any developmental or neurological abnormalities with J.M.G. Id. at ¶ 4.

On July 15, 2014, J.M.G. returned to Dr. Bourne's office for his four-month checkup. Pet. Ex. 6 at ¶ 5. J.M.G.'s head circumference had increased by 6.2 cm since his last visit and Dr. Bourne expressed serious concern about the accelerated head circumference growth. Id. Dr. Bourne recommended J.M.G. see a neurologist. Id. J.M.G. received his second set of vaccinations at this visit. Id.

Petitioner stated, "[i]n the ensuing weeks after his 4 month check-up, we began to notice that J.M.G. seemed to not be as alert as he had been before. He did not respond the same way when we would walk into a room or try and get his attention. These signs were very mild at first, but they progressed." Pet. Ex. 6 at ¶ 6. Previously, J.M.G.'s behaviors included "smiling, looking at both parents directly and without limitations in the movements of his arms." Pet. Ex. 22 at ¶ 5. After July 15, 2014, J.M.G. "did not respond to his name . . . and did not look directly at [petitioner] when [he] called his name." Id. at ¶ 11. "J.M.G. began missing developmental milestones pertaining to speech and motor skills. There was not-so-much a regression of skills, because of the neurological injury, he never initially attained the skill to begin with." Pet. Ex. 6 at ¶ 6. J.M.G. was almost nine months old before he could roll over, fifteen months when he first started to crawl, and twenty months when he first stared to walk. Pet. Ex. 22 at ¶ 11.

Petitioner opined, "[a]s a result of the [] adverse reaction to the various vaccinations he received on May 13, 2014 and on July 15, 2014, J.M.G. has suffered global developmental delays and was slower than expected to hit various developmental milestones, such as sitting up, rolling over, crawling, speaking and walking." Pet. Ex. 6 at ¶ 7. Consequently, "J.M.G. has

been receiving speech and occupational therapy and, although he is slowly improving in his gross and fine motor skills, he is still behind. His speech is very limited, mostly to one-syllable sounds and a limited amount of sign-language." Id.

C. Expert Reports

1. Petitioner's Expert, Cathy Buckley, Ph.D.[9]

Dr. Buckley opined that J.M.G.'s rapid head growth between his two- and four-month well baby checkups was a red flag and should have been reported to the Vaccine Adverse Event Recording System ("VAERS"). Medical Records at 1 (ECF No. 10). She stated that in light of the abnormal head growth, the second dose of DTaP should not have been administered. Id. Dr. Buckley stated that "abnormally rapid head growth is the second most common reportable event in the VAERS database following a DTaP vaccine." Id.

Dr. Buckley explained the aluminum-containing adjuvant added to the DTaP, hepatitis B, Hib, and PCV 13 vaccines "given at the 2-month check-up[] [are] designed to cause a powerful and prolonged immune response by activation of microglial cells and inducing inflammation in the central nervous system." Medical Records at 2 (ECF No. 10). She further stated,

> Microglia are immunological cousins of the macrophages circulating in our bloodstream. When a perceived threat is detected anywhere in the body, macrophages secrete cytokines, or chemical messengers, to recruit other immune cells from many parts of the body. We know that immune cells and the chemicals they secrete can cross the epithelial barrier into the brain. Cytokines, in sufficient numbers, will activate the brain's microglia to withdraw their appendages, transforming them into roaming macrophages that travel around the brain several times in an hour. Rather than prune excess synapses in the brain, as they are designed to do, microglia instead attack and remove cells which have been incorrectly interpreted by the immune system as foreign or unhealthy. In a susceptible subgroup of children, the vaccine can precipitate an acute adverse reaction, leading to pronounced brain inflammation.

Id. "Additionally, aluminum hydroxide adjuvant is a nanoparticle, absorbed by our body's macrophages, which can then easily transport the aluminum hydroxide to the brain because macrophages pass easily through the blood-brain barrier." Id.

Dr. Buckley stated, "[t]he neurotoxicity of aluminum has been well-known since the early 20th century, and the meteoric rise in neurological disorders began shortly after aluminum adjuvant began to be added to pediatric vaccines in 1932." Pet. Ex. 16 at 1. "The bio-

[9] Petitioner did not file a curriculum vitae for Dr. Buckley. However, it does not appear that she has a medical degree. There is no evidence in the record to suggest that she has ever provided medical care or treatment to children or that she is a neurologist. Dr. Buckley filed two letters. Medical Records at 1-2 (ECF No. 10); Pet. Ex. 16. Dr. Buckley did not file any medical literature or cite to J.M.G.'s medical records or any other evidence to support her opinions.

persistence of aluminum in the brain leads to an ongoing, permanent immune system activation in some children, which can cause brain inflammation and rapid head growth. Aluminum studies using vaccine adjuvants have shown both behavioral deficits of motor function as well as cognitive deficits." Id.

Dr. Buckley opined the DTaP vaccine and other aluminum-containing vaccines given to J.M.G. "triggered acute brain inflammation, precipitating his rapid head growth and concomitant developmental delay." Medical Records at 2 (ECF No. 10).

2. Petitioner's Expert, Karen Harum, M.D.

a. Background and Qualifications

Dr. Harum is a board-certified pediatrician who specializes in the area of neurodevelopmental disabilities. Pet. Ex. 11 at 1-3. She attended medical school at the University of Miami School of Medicine and completed her internship at the University of Florida School of Medicine, Shands Teaching Hospital. Id. at 2. Dr. Harum completed her residency in pediatrics at the University of Miami School of Medicine. Id. She then completed a fellowship in neurodevelopmental pediatrics at the Kennedy Krieger Institute, at Johns Hopkins University School of Medicine. Id. at 1-2. Thereafter, she served as a post-doctoral fellow at the Kennedy Krieger Research Institute and received a National Research Service Award in Neuroscience. Id. at 1. Dr. Harum is currently in private practice at the Clinic for Special Children. Id.

b. Opinion

Regarding diagnosis, Dr. Harum opined that J.M.G.'s pattern of development is inconsistent with the diagnosis of benign external hydrocephalus. Pet. Ex. 10 at 2. Referencing Marino et al.,[10] she stated benign external hydrocephalus is characterized by a lack of permanent neurological sequelae. Id. (citing Pet. Ex. 12 at 1). "A transient delay of psychomotor development is common in this condition, but those who demonstrate permanent psychomotor delay do not have a benign condition." Id. In comparison, Dr. Harum concluded that J.M.G. "suffered significant neurological and developmental injury due to the accumulation of spinal fluid and increased intracranial pressures that resulted. The mechanism of injury from increased intracranial pressures is proposed to be ischemic injury to white matter tracts." Id.

Although Dr. Harum opined that J.M.G. had increased intracranial pressures, she did not cite to any of J.M.G.'s medical records to support this opinion. Also, she did not cite to medical records in support of her opinion that J.M.G.'s development delays were caused by increased intracranial pressure.

Dr. Harum cited Marino et al., who conducted a literature review and found "a general consensus that [external hydrocephalus] is correlated to familial predisposition and, in some

[10] Maria Marino et al., Benign External Hydrocephalus in Infants: A Single Centre Experience and Literature Review, 27 Neuroradiology J. 245 (2014).

cases, inheritance." Pet. Ex. 12 at 1. "Studies in the pre-CT era suggested that the most frequent cause of macrocephaly was communicating or non-communicating hydrocephalus." Id. at 3. Subsequently CT scans showed enlarged subarachnoid spaces with mild to moderate or no ventricular dilation. Id. Enlargement of the subarachnoid spaces can indicate several genetic disorders. Id. Genetic disorder "should be considered in patients with enlargement of the subarachnoid spaces who do not fit the expected normal patters of development, or in those patients where the finding does not resolve after 18-24 months of age." Id. The authors stated benign external hydrocephalus "can influence psychomotor or motor retardation and behavioural disorders." Id. Marino et al. did not reference vaccinations.

Dr. Harum noted there "were discrepancies in the documented size of [J.M.G.'s] fontanelle; yet it seemed to reduce in size, and observable pulsations became less prominent, between 8 and 14 months of age." Pet. Ex. 10 at 2. "These findings suggest a reduction in intracranial pressure over this time period. It is theorized that his disease process was mitigated somewhat by the natural maturation of arachnoid villi expected at around 18 months of age." Id. However, Dr. Harum posited that J.M.G.'s continued developmental delays and his global developmental delay suggest pathological communicating hydrocephalus. Id.

According to Dr. Harum, J.M.G. sustained intracranial injury related to high pressure communicating hydrocephalus, "the etiology of which is associated in time and in pathophysiologic mechanisms with his 2 month cluster of vaccines." Pet. Ex. 10 at 2-3. Dr. Harum did not cite any of J.M.G.'s medical records showing that J.M.G. ever had "high pressure communicating hydrocephalus." Dr. Harum opined that "[i]n spite of the abnormality seen in accelerated head growth[,] . . . [J.M.G.] was given the 4 month cluster of vaccines as mandated by the CDC and endorsed by the AAP (American Academy of Pediatrics). This vaccination schedule instills 1225 micrograms of Aluminum at the 2 and 4 month visits, injecting about 245 micrograms/kg on those days." Id. at 1 (citing Pet. Ex. 14 at 3).[11]

In support of her inferences regarding the impropriety of administering vaccines to J.M.G. at four months, Dr. Harum cited an article by Tomljenovic and Shaw. The authors stated that aluminum and mercury, found in vaccines, "negatively affect many of the same biochemical processes and enzymes implicated in the etiology of autism, the potential for a synergistic toxic action is plausible." Pet. Ex. 14 at 3. The authors stated infants have "an immature developing blood brain barrier [that] is more permeable to toxic substances than that of an adult." Id. Within the first few years of postnatal life, "exposure to neurotoxic insults may induce CNS damage." Id. They added that "[a]luminum adjuvants are exceptionally potent simulators of the immune system" and can stimulate cytokine response. Id. at 4. Additionally, they stated "aluminum is a [blood brain barrier] neurotoxin that has a propensity to activate brain microglia and increase the production of inflammatory cytokines thereby instigating and/or exacerbating inflammation and excitotoxicity in the brain." Id. at 5.

Dr. Harum postulated that the vaccinations J.M.G. received at two months "triggered an inflammatory and oxidizing response in the brain, characterized as Aluminum hydroxide

[11] Lucija Tomljenovic & Christopher A. Shaw, Aluminum Vaccine Adjuvants: Are They Safe?, 18 Current Med. Chemistry (2011). Petitioner did not file the full article.

mediated disruption of the blood brain barrier, infiltration of leptomeninx by macrophages and lymphocytes, and perivascular lymphocytic infiltration, damaging brain function at multiple levels [] including arachnoid granulation function." Pet. Ex. 10 at 3. "Pro-inflammatory cytokines and other molecules expressed after vaccination can permeate the immature blood brain barrier and cause further inflammatory mediated injury. Polyangiitis and granulomatosis are reported in the medical literature and in VAERS, to be causally related to hepatitis B vaccines and to [flu] vaccines." Id. To support her propositions, Dr. Harum cited Agmon-Levin et al.[12] The authors stated "[v]accines include adjuvants, which are used to stimulate the immune system, preferably without having any specific antigenic effect of their own." Pet. Ex. 15 at 2.[13]

Dr. Harum believed that "a small vessel vasculitis/angiitis characterized by macrophage and lymphocyte infiltration likely occurred at the arachnoid villi, thereby impeding [J.M.G.]'s ability to absorb cerebrospinal fluid at the normal rate." Pet. Ex. 10 at 3. This led "to an accumulation of cerebrospinal fluid and neurological impairment via compression of developing cortical neurons." Id.

Addressing autism, Dr. Harum stated J.M.G.'s large head circumference may be similar to other children diagnosed with autism spectrum disorder. Pet. Ex. 10 at 3. "However, that head growth trajectory usually normalizes by 2 years of age, and the ultimate head circumference at that age is within normal, or high normal limits." Id. She asserted that J.M.G.'s growth pattern did not follow growth patterns seen in the autistic population. Id.

Dr. Harum concluded that "[b]ut for the 2 month cluster of vaccines administered to [J.M.G.], he would have likely progressed as his mother did with larger than average head size, truly benign external hydrocephalus, and normal developmental and intellectual capacity." Pet. Ex. 10 at 3.

3. Respondent's Expert, Peter M. Bingham, M.D.

a. Background and Qualifications

Dr. Bingham is board certified in pediatric neurology. Resp. Ex. A at 1. He received his undergraduate degree in biology, cum laude, from Harvard College and his M.D. from Columbia College of Physicians & Surgeons. Resp. Ex. B at 1. He is a Professor of Neurology & Pediatrics at the University of Vermont and a Fulbright Scholar. Id. He has published over 40 medical articles and book chapters. Id. at 3-7. He has 25 years of post-residency experience in general child neurology where he has diagnosed and managed approximately 50 cases of encephalopathy or infectious/inflammatory brain disease in newborns and young infants and has evaluated at least 100 infants with macrocrania. Resp. Ex. A at 1.

[12] Nancy Agmon-Levin et al., Vaccines and Autoimmunity, 5 Nat. Rev. Rheumatology 648 (2009).

[13] The article does not appear to discuss polyangiitis, granulomatosis, small vessel vasculitis/angiitis characterized by macrophage and lymphocyte infiltration, or lend further support to Dr. Harum's contentions.

b. Opinion

Dr. Bingham agreed with J.M.G.'s treating neurologist, Dr. Cokely, that J.M.G. had familial external hydrocephalus. Resp. Ex. A at 2. Dr. Bingham stated, "[c]linical reports of external hydrocephalus, which often runs familial, indicate that in many cases there are neurodevelopmental difficulties in these patients, even in those where there is a positive family history of macrocrania[14]." Id. Dr. Bingham cited Wiig et al.,[15] who noted benign external hydrocephalus "is the most common hydrocephalic condition in young children." Resp. Ex. A, Tab 3 at 5. In a Norway population-based study, the incidence of the condition was 0.4 per 1000 live births. Id. at 3. Dr. Bingham opined that the condition does not cause increased intracranial pressure and delays or impairments. Resp. Ex. A at 2.

Dr. Bingham opined it is difficult to conclude whether there is a causal association between external hydrocephalus and J.M.G.'s developmental delays. Resp. Ex. A at 2. Dr. Bingham also noted "[t]he fact that JMG walked relatively late—at 20 months—yet was later not remarked to have particular motor disability fits with the observed transient gross motor delay that is often seen in external hydrocephalus." Id.

In infants who have external hydrocephalus, Dr. Bingham explained that there can be variable head circumferences. Resp. Ex. A at 2. "[S]ome infants with external hydrocephalus are born with normal [] head circumference, while others have a macrocrania at birth. Among those who have normal-range head circumference at birth, the acceleration in head growth that leads to the clinical recognition of their macrocrania can and does often occur within the first three months of life, as occurred for [J.M.G.]." Id. Dr. Bingham cited Alvarez et al.,[16] to support his opinions on the clinical course and variability of head circumference size in infants with external hydrocephalus. Id.

In Alvarez et al., the authors studied a population of 36 infants who had idiopathic external hydrocephalus. Resp. Ex. A, Tab 1 at 1. The study found that overall external hydrocephalus was a benign condition that resolves spontaneously and is closely related to benign familiar macrocephaly. Id. at 6. The rates of head circumference growth of the infants varied from the 25th percentile to greater than the 95th percentile at birth. Id. at 3. Thirty-two of the 36 infants were developmentally normal, while three were mildly delayed in gross motor development, and one infant was moderately globally delayed. Id. at 5. There was a family history of macrocephaly in 88% of cases. Id. at 4.

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[14] Macrocrania is the "abnormal increase in the size of the skull, the facial area being disproportionately small in comparison." Macrocrania, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=29232 (last visited Mar. 8, 2022).

[15] Ulrikke S. Wiig et al., Epidemiology of Benign External Hydrocephalus in Norway—A Population-Based Study, 73 Pediatric Neurology 36 (2017).

[16] Luis A. Alvarez et al., Idiopathic External Hydrocephalus: Natural History and Relationship to Benign Familial Macrocephaly, 77 Pediatrics 901 (1986).

Dr. Bingham disagreed with Dr. Harum about the nature and cause of J.M.G.'s familial external hydrocephalus. Dr. Bingham opined that J.M.G.'s head growth acceleration was consistent with benign external hydrocephalus. Resp. Ex. A at 3.

Although familial or benign external hydrocephalus is labeled as "benign," Dr. Bingham explained that this designation is somewhat misleading. Resp. Ex. A at 3. Dr. Bingham cited the Yew et al.[17] and Zahl et al.[18] articles to show that a significant number of infants with external hydrocephalus do have neurodevelopmental difficulties. Id. Yew et al. stated that while patients with benign external hydrocephalus generally had presenting motor delays, "new verbal delays were detected in a non-trivial number of patients." Resp. Ex. A, Tab 2 at 1. Additionally, Yew et al. found the most common deficit was in gross motor development and while developmental delay generally improved, several children had persistent deficits. Id. at 4. In the study, "a quarter diagnosed with gross motor delay did not improve, and new verbal delays were noted in 6 patients" out of 65 patients. Id. at 5.

Likewise, Zahl et al., a systematic review of literature and cases, reported that a "substantial number of patients show temporary or permanent psychomotor delay." Resp. Ex. A, Tab 4 at 1. Dr. Bingham cited this article to illustrate that children affected long-term failed to reach developmental milestones, especially in gross motor function, as well as speech or language delay. Id. at 5. Additionally, the "symptoms related to increased intracranial pressure, which often can be seen initially, all appear to be absent at follow-up." Id.

Regarding the references in J.M.G.'s records concerning autism, Dr. Bingham stated the diagnosis does not appear to have been made, though it seems to have been considered. Resp. Ex. A at 3. He disagreed with Dr. Harum's statements that head size in autism patients normalizes by age two. Id.

With regard to Dr. Buckley's opinions, Dr. Bingham disagreed J.M.G. "had significant brain inflammation—from any cause—during his first 4 months of life." Resp. Ex. A at 3-4. Dr. Bingham explained that J.M.G.'s clinical course was not consistent with acute inflammation for a number of reasons. Id. at 3. First, J.M.G. did not have acute encephalopathy. Id. Second, there was no evidence of seizures. Id. Third, newborns or young infants who have brain inflammation do not have accelerated growth of their head circumference unless they suffer hydrocephalus as a complication of their illness. Id. Since the records did not show any sign of deterioration or acute hydrocephalus, there is no evidence to suggest that J.M.G. had such a degree of inflammation as would cause hydrocephalus. Id. This was especially true since

[17] Andrew Y. Yew et al., Long-Term Health Status in Benign External Hydrocephalus, 47 Pediatric Neurosurgery 1 (2011).

[18] Sverre M. Zahl et al., Benign External Hydrocephalus: A Review, with Emphasis on Management, 34 Neurosurgery Rev. 417 (2011).

J.M.G.'s first neurological examination documented that he was "doing well" developmentally. Id.[19]

Moreover, J.M.G.'s MRI and head ultrasounds did not show evidence of parenchymal brain injury. Resp. Ex. A at 4. Dr. Bingham explained that these diagnostic studies would show evidence of brain injury if J.M.G. had suffered brain injury from acute inflammation. Id.

Finally, concurrent with J.M.G.'s accelerated head growth, his length and weight also showed acceleration. Resp. Ex. A at 4. Dr. Bingham opined that "[e]ven if there was not a precise concordance in the respective anthropometric percentiles and degree of acceleration, the correspondence of his length and weight parameters to his head circumference suggest growth of healthy tissue, rather than some purported accumulation of tissue/body mass owing to inflammation within the skull," as Dr. Buckley suggested. Id.

Dr. Bingham concluded that J.M.G.'s macrocrania was familial in nature. Resp. Ex. A at 4. In addition, J.M.G. has developmental delay with communication difficulty and autistic features. Id. Dr. Bingham concluded that "[t]here is not a clear connection between JMG's macrocrania and his developmental problems; the cause of his developmental problems is uncertain, but was not due to the vaccinations he received." Id.

4. Respondent's Expert, Joseph N. Blattman, Ph.D.

a. Background and Qualifications

Dr. Blattman is an Associate Professor in the Center for Immunotherapy, Vaccines & Virotherapy in The Biodesign Institute at Arizona State University ("ASU") as well as in the ASU School of Life Sciences. Resp. Ex. C at 1. His Ph.D. training was at Emory University in Immunology and Molecular Pathogenesis. Id. Dr. Blattman's post-doctoral training was at the University of Washington and Fred Hutchinson Cancer Research Center on immunotherapy approaches to improve cancer therapies. Id. Previously he was an Assistant Professor in the Center for Infectious Diseases and Vaccinology at ASU. Id. He was also a Research Assistant Professor in the Department of Immunology at the University of Washington School of Medicine, where he was Director of an Immunological Correlates of Protection core laboratory associated with the Collaboration for AIDS Vaccine Discovery program supported by the Bill & Melinda Gates Foundation. Id. Dr. Blattman has published over 30 peer-reviewed articles. Resp. Ex. D at 5-7.

b. Opinion

Dr. Blattman responded to the opinion letter and report submitted by Drs. Buckley and Harum. Resp. Ex. C at 3. Dr. Blattman stated that "[b]ased upon my training, education, and

[19] Dr. Cokely also stated, "likely, this is a genetic condition based upon mom's history and he has just delayed absorption of spinal fluid in the subarachnoid space." Medical Records at 72 (ECF No. 10). Dr. Cokely did not document that J.M.G. had any adverse reaction to his prior vaccinations.

extensive experience in the field of immunology, the underlying immunobiology [that Dr. Buckley] describes is not accurate nor does it provide a reliable theory to implicate the role of a vaccination in this case." Id.

Dr. Blattman specifically disputed Dr. Buckley's claim that the "aluminum-containing adjuvant included in the DTaP vaccine," as well as others, "is designed to cause a powerful and prolonged immune response by activation of microglial cells and inducing inflammation in the central nervous system" as untrue. Resp. Ex. C at 3 (citing Medical Records at 2 (ECF No. 10)).

While he agreed that the "Alum adjuvant is a potent stimulator of macrophages and has been shown to be a potent stimulator of B cells," Dr. Blattman explained that "this is within the context of the draining lymph nodes of the site of vaccine injection, [and] not the central nervous system." Resp. Ex. C at 3. Dr. Blattman emphasized that "there is no published literature involving an in vivo study in humans that supports the concept that an aluminum adjuvant can trigger CNS inflammation." Id. Instead, the adjuvant improves the process that leads to vaccine induced immunity. Id.

Dr. Blattman also disagreed with Dr. Buckley's assertions regarding the VAERS database. Resp. Ex. C at 3. Dr. Buckley stated that "abnormally rapid head growth is the second most common reportable event in the VAERS database following a DTaP vaccine." Medical Records at 1 (ECF No. 10). Dr. Blattman reviewed the VAERS database and found that abnormal rapid head growth was reported in less than 0.01% of all cases reporting macrocephaly as an adverse event. Resp. Ex. C at 3. Additionally, he explained that the VAERS database is a passive reporting system; therefore, one cannot use the data from it to prove causation. Id.

In response to Dr. Harum's expert report, Dr. Blattman deferred to Dr. Bingham regarding J.M.G.'s diagnosis. Resp. Ex. C at 3. However, Dr. Blattman disagreed with Dr. Harum's assertions that Alum could contribute to intracranial inflammation or rapid head circumference increase, finding that such opinions are speculative. Id. Dr. Blattman stated that "[t]here is no published literature to support Dr. Harum's opinion regarding such intracranial inflammation triggered by Alum." Id.

In conclusion, Dr. Blattman opined that "to a reasonable degree of medical and scientific probability [] the vaccines at issue in this case played no causative role in J.M.G.'s alleged conditions." Resp. Ex. C at 4.

IV. LEGAL FRAMEWORK

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccines at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). However, the court cannot accept "cursory, conclusory opinions." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994); see also Fadelalla v. Sec'y of Health & Hum. Servs., No. 97-573V, 1999 WL 270423, at *6 (Fed. Cl. Spec. Mstr. Apr. 15, 1999), mot. for rev. denied, 45 Fed. Cl. 196 (1999). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

Expert testimony, in particular, must have some objective scientific basis in order to be credited by the special master. Terran v. Sec'y of Health & Hum. Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999); Jarvis v. Sec'y of Health & Hum. Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322); Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010). When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. denied & decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). Special Masters cannot rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

B. Failure to Prosecute

When a petitioner fails to comply with Court orders to prosecute his case, the court may dismiss the case. Sapharas v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 503 (1996); Tsekouras v. Sec'y of Health & Hum. Servs., 26 Cl. Ct. 439 (1992), aff'd, 991 F.2d 819 (Fed. Cir. 1993); Vaccine Rule 21(c); see also Claude E. Atkins Enters., Inc. v. United States, 889 F.2d 1180, 1183 (Fed. Cir. 1990) (affirming dismissal of case for failure to prosecute for counsel's failure to submit pre-trial memorandum); Adkins v. United States, 816 F.2d 1580, 1583 (Fed. Cir. 1987) (affirming dismissal of cases for failure of party to respond to discovery requests). Petitioner's failure to file an expert report and failure to file any medical records indicates a disinterest in pursuing the claim.

Cases that have been dismissed for failure to file medical records and expert reports include, but are not limited to: Wansaw v. Sec'y of Health & Hum. Servs., No. 10-246V, 2014 WL 1912735 (Fed. Cl. Spec. Mstr. Apr. 22, 2014); Plaisance v. Sec'y of Health & Hum. Servs.,

No. 12-430V, 2014 WL 6609749 (Fed. Cl. Spec. Mstr. Oct. 10, 2014); Button ex rel. W.S.B. v. Sec'y of Health & Hum. Servs., No. 16-1391V, 2017 WL 2876099 (Fed. Cl. Spec. Mstr. June 5, 2017); Soghomonian ex rel. K.S. v. Sec'y of Health & Hum. Servs., No. 15-1292V, 2018 WL 1834889 (Fed. Cl. Spec. Mstr. Feb. 21, 2018), determination sustained, 139 Fed. Cl. 227 (2018); Beyerl v. Sec'y of Health & Hum. Servs., No. 20-32V, 2022 WL 289213 (Fed. Cl. Spec. Mstr. Jan. 6, 2022).

C. Motion for Recusal

28 U.S.C. § 455 sets forth the standard and circumstances under which any federal justice, judge, or magistrate (and thus, by extension, a special master) shall recuse him or herself. 28 U.S.C. § 455 (2017); see also Schultz v. Sec'y of Health & Hum. Servs., No. 16-539V, 2019 WL 6359139, at *3 (Fed. Cl. Spec. Mstr. Oct. 9, 2019). In relevant part, the statute reads:

> (a) Any justice, judge, or magistrate of the United States shall disqualify himself in any proceeding in which his impartiality might reasonably be questioned.
>
> (b) He shall also disqualify himself in the following circumstances:
>
> (1) Where he has a personal bias or prejudice concerning a party, or personal knowledge of disputed evidentiary facts concerning the proceeding. . . .

28 U.S.C. §§ 455(a)-(b). It is well-established that this statute is to be applied objectively. Recusal is required only "if a reasonable person who knew the circumstances would question the judge's impartiality, even though no actual bias or prejudice has been shown." Fletcher v. Conoco Pipe Line Co., 323 F.3d 661, 664 (8th Cir. 2003) (citing United States v. Tucker, 78 F.3d 1313, 1324 (8th Cir. 1996)).

The statute was the subject of a notable United States Supreme Court case. In United States v. Grinnell Corp., 384 U.S. 563 (1966), the Supreme Court set forth the outline of what would later be known as the extrajudicial source doctrine. In Grinnell Corp., the defendants sought the disqualification of a district court judge under 28 U.S.C. § 144—the statutory basis for recusal of district court judges and counterpart to 28 U.S.C. § 4559—based on comments made during a series of pretrial conferences. Id. at 581-82. Ultimately, the Supreme Court ruled that "[t]he alleged bias and prejudice to be disqualifying must stem from an extrajudicial source and result in an opinion on the merits on some basis other than what the judge learned from his participation in the case." Id. at 583 (citing Berger v. United States, 255 U.S. 22, 31 (1921)).

The applicability of the extrajudicial source doctrine was later extended in Liteky v. United States. 510 U.S. 540, 541 (1994). In Liteky, claimants moved to disqualify a district judge before whom they had appeared in a previous matter. Id. They argued that recusal was appropriate under 28 U.S.C. § 455(a) because "the judge had displayed 'impatience, disregard for the defense and animosity' towards [petitioners]" during the previous trial. Id. at 542. The district judge denied the motion for disqualification on the grounds that "matters arising from

judicial proceedings were not a proper basis for recusal," and later denied it a second time. Id. at 543.

The claimants later appealed, claiming that the district judge's refusal to recuse himself violated 28 U.S.C. § 455(a). Liteky, 510 U.S. at 542. The Eleventh Circuit affirmed the convictions of willfully injuring federal property, again relying on the extrajudicial source doctrine. Id. In an opinion written by Justice Scalia, the Supreme Court found that "judicial rulings alone almost never constitute a valid basis for a bias or partiality motion." Id. at 555 (citing Grinell Corp., 384 U.S. at 583). Expanding on the above, the Supreme Court added:

> [O]pinions formed by the judge on the basis of facts introduced or events occurring in the course of the current proceedings, or of prior proceedings, do not constitute a basis for a bias or partiality motion unless they display a deep-seated favoritism or antagonism that would make fair judgment impossible. Thus, judicial remarks during the course of a trial that are critical or disapproving of, or even hostile to, counsel, the parties, or their cases, ordinarily do not support a bias or partiality challenge. They may do so if they reveal an opinion that derives from an extrajudicial source, and they will do so if they reveal such a high degree of favoritism or antagonism as to make fair judgment impossible.

Id. The Court also described the type of expressions that do not rise to the level of favoritism or antagonism required to establish bias or partiality. Such expressions include those of "impatience, dissatisfaction, annoyance, and even anger." Id. at 555-56. Lastly, the Court explained that "judicial rulings, routine trial administration efforts, and ordinary admonishments" are inadequate grounds on which to support a motion for recusal. Id. at 556.

A few years after Liteky, the Federal Circuit addressed the issue of recusal under 28 U.S.C. § 455(a). See Charron v. United States, 200 F.3d 785, 787 (Fed. Cir. 1999). In Charron, the plaintiffs sought the recusal of the presiding judge in a Court of Federal Claims proceeding based largely upon the judge's alleged treatment of their counsel. Id. at 788. To support their argument, the plaintiffs cited several instances where the judge accused the attorney of "malpractice, defrauding the court, filing frivolous action, and doctoring the record." Id. at 789. In reviewing the issue, the Federal Circuit noted that "[o]rdinarily an allegation of judicial bias relates to bias against a party. Although it is possible that judicial bias against the lawyer may become so pervasive and clear that the client's rights are likely to be affected." Id. at 788 (citing Rosen v. Sugarman, 357 F.2d 794, 798 (2d Cir. 1966)). However, the Federal Circuit found that "[t]he judicial comments and actions upon which the [plaintiffs] rely. . . merely reflect [the judge's] evaluation and criticism of [the attorney's] handling of the cases and her perception that his professional performance was severely deficient." Id. at 789. Thus, because the judge's opinions were formed within the confines of the litigation, consistent with Liteky, the extrajudicial source doctrine was applied, and the denial of the plaintiffs' motion for recusal was affirmed. Id.

Motions seeking recusal of special masters are exceedingly rare. Of the limited number of cases in which recusal of a special master was sought, the overwhelming majority were found to be frivolous, meritless, or otherwise made in anticipation of, or retaliation for, unfavorable

rulings. See, e.g., Byrd v. Sec'y of Health & Hum. Servs., No. 17-900V, slip op. (ECF No. 42) (Fed. Cl. Spec. Mstr. June 6, 2018), mot. for review denied, 142 Fed. Cl. 79, 86 (2019) (denying petitioner's motion for recusal "because it lack[ed] any factual or legal merit"), aff'd, 778 F. App'x 924 (Fed. Cir. 2019); Padmanabhan v. Sec'y of Health & Hum. Servs., No. 11-141V, slip op. at 2 (ECF No. 42) (Fed. Cl. Spec. Mstr. Sept. 26, 2013) (denying request for recusal where petitioners alleged that a special master's use of a literary reference in a previously decided, but unrelated, case evidenced prejudice against autism claims); Earles v. Sec'y of Health & Hum. Servs., No. 10-34V, 2011 WL 1979609, *1 (Fed. Cl. Spec. Mstr. Apr. 22, 2011) (declining to grant petitioner's motion for recusal for lack of evidence to support allegations of hostility and animosity towards petitioner and finding that much of the complained of communications merely reflected the special master's efforts to manage her docket); Doe v. Sec'y of Health & Hum. Servs., 2007 WL 2350645, *1 (Fed. Cl. Spec. Mstr. July 31, 2007) (denying petitioner's motion for recusal where petitioner cited the special master's comments during a Rule 5 status conference as the basis for recusal); Wallace v. Sec'y of Health & Hum. Servs., No. 97-836V, 2005 WL 3132463, *1, *1 n.3 (Fed. Cl. Spec. Mstr. Oct. 28, 2005) (declining to grant petitioner's motion for recusal for a claim that was dismissed by one special master and later remanded to another following a successful motion for relief from judgment).

D. Motion to Vacate or Delay Deadlines

The Vaccine Rules of the United States Court of Federal Claims, which are found at Appendix B to the RCFC, govern all Program proceedings. Vaccine Rule 1(a). Vaccine Rule 19(b)(1) provides, "[t]he special master or the court may grant a motion for an enlargement of time for good cause shown except when such an extension is prohibited by these rules." Vaccine Rule 19(b)(1).

RCFC 6(b) provides:

> (1) In General. When an act may or must be done within a specified time, the court may, for good cause, extend the time:
>
> > (A) with or without motion or notice if the court acts, or if a request is made, before the original time or its extension expires; or
> >
> > (B) on motion made after the time has expired if the party failed to act because of excusable neglect.
>
> (2) Exceptions. The court must not extend the time to act under RCFC 52(b), 59(b), (d), and (e), and 60(b).

RCFC 6(b).

E. Alternative Basis for Dismissal

Although there are ample grounds to dismiss this case for failure to prosecute, a special master may elect to rule in the alternative. See Padmanabhan v. Sec'y of Health & Hum. Servs.,

No. 11-141V, 2015 WL 1736345, *23 (Fed. Cl. Spec. Mstr. Mar. 26, 2015) (electing to dismiss petitioners' case for failure to prosecute and after an analysis of Althen causation sua sponte), aff'd, 638 F. App'x 1013 (Fed. Cir. 2016). In so doing, a special master may treat petitioner's refusal to file additional evidence and his assertion he has established entitlement to compensation as the functional equivalent of a motion for Ruling on the Record.

In Padmanabhan, pro se petitioners, parents of a minor, filed petition alleging that the MMR, DTaP, Hib, and varicella vaccines significantly aggravated a preexisting mitochondrial disease. 2015 WL 1736345, at *1. The case continued for four years without petitioners filing complete medical records requested by the special master. Id. The records filed indicated that petitioners' son was diagnosed with autism spectrum disorder, but that he was never diagnosed with mitochondrial disease. Id. Petitioners refused to comply with numerous court orders and filed multiple orders for the special master to recuse herself and to suspend proceedings. Id. at *2. After multiple warnings, the special master dismissed the case for failure to prosecute. Id. The special master also conducted an Althen analysis "treating petitioners' assertions that the record establishes entitlement to compensation as either a motion for summary judgment or a motion for a ruling on the record." Id. at *6.

The Vaccine Act requires that the Vaccine Rules provide "the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations cross examinations, or hearings." § 12(d)(2)(D). Thus, a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d).

In ruling on the record, a special master may decide controverted questions of fact and make conclusions of law. See Vaccine Rule 8(d). Congress has instructed special masters to "be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim." H.R. Rep. No. 99-908, at 17 (1986), reprinted in 1986 U.S.C.A.N. 6344, 6358.

To receive compensation through the Program, petitioner must prove either (1) that J.M.G. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that J.M.G. suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that J.M.G. suffered a Table Injury, he must prove that a vaccine J.M.G. received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and his injury ("Althen Prong Three"). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or

by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

"Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred." LaCour v. Sec'y of Health & Hum. Servs., No. 90-316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); accord Burns v. Sec'y of Health & Hum. Servs., No. 90-953V, 1992 WL 365410, at *6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff'd, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Id.; see also de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008).

V. ANALYSIS

A. Dismissal for Failure to Prosecute

The Vaccine Program has past precedent for dismissing cases due to failure to prosecute with deficient expert reports. See, e.g., Stachlewitz ex rel. H.G.S. v. Sec'y of Health & Hum. Servs., No. 13-220V, 2014 WL 5293629 (Fed. Cl. Spec. Mstr. Sept. 23, 2014); Duncan v. Sec'y of Health & Hum. Servs., No. 16-1367V, 2020 WL 6738118 (Fed. Cl. Spec. Mstr. Oct. 19, 2020), mot. for rev. denied, 153 Fed. Cl. 642 (2021). In Stachlewitz, petitioner had over a year to file an expert report to refute the expert opinions of respondent's expert. 2014 WL 5293629, at *4. Petitioner failed to file an expert report to support petitioner's burden of proof and the case was dismissed. Id. at *5. In Duncan, petitioner's case was dismissed for insufficient evidence. 153 Fed. Cl. at 648. Petitioner filed expert reports with numerous deficiencies and failed to cure the inadequacies in the record despite numerous opportunities to do so. Id. at 659.

On March 4, 2022, respondent filed a motion for either a renewed order to show cause or to dismiss the case for failure to prosecute pursuant to the December 23, 2021 Order to Show Cause. Resp. Mot. for Order to Show Cause. Petitioner responded to respondent's motion on March 9, 2022. Pet. Response. Petitioner alleged respondent's motion was "a coordinated effort" between the undersigned and respondent to dismiss this case. Id. at 1. Petitioner opined, "[t]o an objective observer, granting [r]espondent's motion in light of [petitioner's motion for

recusal] could be considered an effort to sidestep justice and give a 'Chilling Effect' to anyone seeking a fair trial in the Vaccination Court." Id. (emphasis omitted). Additionally, petitioner stated, he has already shown cause for this case because he filed:

- The submission of medical records showing injury to the Child.
- Handwritten vaccination records showing gross physician errors in the scheduling of Child's mandatory vaccinations.
- Neurologist Records.
- MRI Report
- Expert Witness Dr. Buckley PHD.
- Expert Witness, Pediatric Neurologist, Dr. Har[]um.

Id. Petitioner stated, he has "provided the court with two exceptional Experts who have carefully and thoughtfully explained the issue at hand to the Court. There is no possible way that Special Master Nora Beth Dorsey is treating the evidence or the [p]etitioner fairly. The [r]espondent's Motion should [not] be granted." Id. at 4 (emphasis omitted).

As stated previously and in greater detail below, the undersigned finds Dr. Harum's and Dr. Buckley's expert reports conclusory, insufficient, and lacking in evidentiary support. On March 5, 2020, petitioner requested to file another expert report, which the undersigned granted because petitioner had already paid $2,000.00 to retain an expert. The undersigned also requested updated medical records from J.M.G.'s pediatric neurologist. Despite petitioner requesting to file an additional expert report, he has failed to do so.

Here, petitioner had two years to file medical records and an expert report. Petitioner has repeatedly failed to do so. Due to the COVID-19 pandemic, the undersigned has granted numerous motions for extension of time to allow petitioner to obtain and file J.M.G.'s medical records and an expert report. However, petitioner has not attempted to comply with any of the prior orders. Petitioner has also failed to even partially comply by filing updated medical records. As such, petitioner has failed to prosecute the case. The undersigned has repeatedly warned petitioner that failure to file the requested medical records and an expert report will result in the dismissal of the petition for failure to prosecute.

As in Stachlewitz and Duncan, the undersigned repeatedly warned petitioner his expert reports were insufficient to prove causation. The undersigned has given petitioner over two years to file an expert report that comported with the Althen prongs. However, petitioner has failed to cure the inadequacies of the expert reports or to file updated medical records.

Therefore, the undersigned **GRANTS** respondent's motion for an order to show cause and dismisses petitioner's case for failure to prosecute.

B. Motion for Recusal

Having considered the overall circumstances of the present matter, the undersigned finds the motion for recusal is not warranted. No evidence has been presented which shows that the undersigned has previously demonstrated any specific bias against petitioner or his past counsel

in the present case.

In his current motion for recusal, petitioner reiterated he did not give consent to convert the status conference on May 23, 2019, into a Rule 5 conference. Pet. Mot. for Recusal at 1. However, the undersigned did obtain consent of the parties prior to providing her evaluation of the evidence. The Rule 5 Order specifically notes that consent was obtained. Rule 5 Order at 1.

Petitioner also stated, "[p]etitioner specifically instructed Attorney David P. Murphy to request that the May 23, 2019, status conference be recorded." Pet. Mot. for Recusal at 1 (emphasis omitted). Petitioner asserts that it was "grossly unfair to not record a conference call when the [p]etitioner specifically instructed that it be recorded." Id. However, the parties did not request that the conference be recorded. Further, the substance of the Rule 5 conference was recorded in the subsequent Rule 5 Order which issued and available to the parties.

Petitioner next complained that it was "grossly unfair to convert a status conference to a Rule 5 conference without giving prior notice." Pet. Mot. for Recusal at 1. However, the parties consented to the Rule 5 conference, and did not express any concerns that the conference was unfair. Therefore, the undersigned declines to recuse herself based on petitioner's assertions related to the Rule 5 conference, or due to assertions that the undersigned made "inaccurate statements" that "demonstrate a lack of objectivity and impartiality." Id.

Moreover, petitioner's recusal motion relies on subjective statements concerning procedural actions during the Rule 5 conference to establish bias. This motion does not provide a basis for recusal under the standard set forth in Section 455. The substance of the undersigned's ruling on reasonable basis, and lack of a recording, is not grounds for recusal. As the Supreme Court instructs in Liteky, "judicial rulings alone almost never constitute a valid basis for a bias or partiality motion." 510 U.S. at 555. Nor do individual statements contained therein and protested by petitioner evince or reflect a deeply-held or long-standing bias against petitioner or his former counsel that would inhibit the undersigned from fairly deciding entitlement. Accordingly, the purported basis for recusal does not constitute the kind of extrajudicial evidence of bias contemplated in Grinell Corp. and Liteky. See Grinell Corp., 384 U.S. at 583; Liteky, 510 U.S. at 555. Therefore, the undersigned **DENIES** petitioner's motion for recusal.

C. Motion to Vacate or Delay Deadlines

Petitioner requested to vacate or delay the deadline for production of updated medical records and expert reports, until after the Motion to Recuse has been settled. Pet. Mot. to Vacate at 1. Vaccine Rule 19(b) provides that "[t]he special master of the court may grant a motion for an enlargement of time for good cause shown except when such an extension is prohibited by these rules." RCFC, Appendix B, Rule 19(b)(1).

Petitioner cites the death of his father and sister and the COVID-19 pandemic lockdowns and quarantines as circumstances that would not allow him to file updated medical records and an expert report. Pet. Mot. to Vacate at 1.

Specifically, in his motion, petitioner stated,

> As a result of the following list of events, [p]etitioner was unable to produce the requested materials:
> • Covid-19 OMICRON Variant – Highly contagious and limited hospital room space available now.
> • Covid-19 DELTA Variant – Highly lethal for certain individuals.
> • The April 2021 death of Petitioner's Father.
> • Subsequent Period of Mourning of Petitioner's Father.
> • The February 2021 death of Petitioner's Sister.
> • Subsequent Period of Mourning of Petitioner's Sister.
> • Lockdown of The County of Los Angeles #1.
> • Lockdown of The County of Los Angeles #2.
> • Quarantines of school children who had been exposed to other children who tested positive for COVID at Petitioner's son's school.

Pet. Mot. to Vacate at 1. Petitioner continued stating, "[r]equiring [p]etitioner to produce updated medical records and expert reports by February 22, 2022, is overburdensome and unnecessary given the unavoidable and extraordinary set of personal hardships and Pandemic related events outside of the [p]etitioner's control." Id.

Respondent filed a response to petitioner's second motion to vacate on March 4, 2022. Resp. Response to Pet. Second Mot. to Vacate. Respondent stated, "[p]etitioner did not contact respondent regarding the subject motion. Respondent objects to the motion." Id. at 1. Respondent argued that Covid-19 related issues and personal hardships "have not stalled [other] cases for two calendar years." Id. at 2. Respondent stated, "[a]ccordingly, given that petitioner has had two years to comply with the special master's initial order, petitioner's motion for extension should be denied." Id.

On March 9, 2022, petitioner filed a response to respondent's objection to petitioner's second motion to vacate deadlines stating, "several times previously in this same case . . . petitioner has made motions for deadline extensions, without previously consulting the [r]espondent's counsel, and the extra-time was granted. This created an estoppel." Pet. Reply at 1 (emphasis omitted). Additionally, petitioner stated that respondent has made motions without contacting petitioner before they were granted. Id. Petitioner provided "reasons for needing a time extension are clear and reasonable. If [respondent] had a legitimate dispute with the reasons being cited for the time extension, she should make that argument; she failed to do this." Id.

Vaccine Rule 19(b)(3) states, "the moving party must make a reasonable effort to discuss the motion with opposing counsel and must indicate in the motion whether an opposition will be filed, or, if opposing counsel cannot be consulted, an explanation of the efforts that were made to do so," prior to filing a motion for extension of time. Failure to do so does not create estoppel. Moreover, the undersigned has routinely emailed respondent for respondent's position on petitioner's motion prior to granting petitioner's motion due to petitioner's failure to make reasonable effort to contact respondent prior to filing motions for extension of time. See, e.g., Order dated Mar. 29, 2021; Order dated Jan. 27, 2021; Order dated Dec. 3, 2020.

On March 5, 2020, the undersigned requested that petitioner file medical records and an expert report that comported with the Althen prongs. The undersigned recognizes the hardships that petitioners have faced due to Covid, especially as it pertains to obtaining updated medical records and expert reports. However, two years have now passed, and petitioner has not even filed the requested medical records essential to the claim, those by J.M.G.'s pediatric neurologist, and has not filed an expert report. The undersigned has repeatedly warned petitioner that failure to file the requested medical records and an expert report will result in the dismissal of the petition. Therefore, the undersigned **DENIES** petitioner's motion to vacate deadlines to file medical records and an expert report.

D. Alternative Basis for Dismissal

Although there are ample grounds to dismiss this case for failure to prosecute, the undersigned has reviewed all of the medical records, expert reports, medical literature, and all evidence filed in this matter in accordance with the relevant legal standards with regard to causation. See Padmanabhan, 2015 WL 1736345, at *23. In so doing, the undersigned treats petitioner's failure to file additional evidence as the functional equivalent of a motion for Ruling on the Record.

1. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Petitioner's experts provided unpersuasive and conclusory opinions. First, because Dr. Buckley's CV was never filed, the undersigned could not properly evaluate whether Dr. Buckley was qualified to opine on these matters. Moreover, Dr. Buckley proposed a novel theory, which was not supported by scientific and medical evidence. In addition, her opinions were often conclusory.

Without citing medical literature or evidence, Dr. Buckley opined the DTaP, and other aluminum-containing vaccines given to J.M.G., "triggered acute brain inflammation,

precipitating his rapid head growth and concomitant developmental delay." Medical Records at 2 (ECF No. 10). The aluminum-containing adjuvant added to the DTaP, hepatitis B, Hib, and PCV 13 vaccines are "designed to cause a powerful and prolonged immune response by activation of microglial cells and inducing inflammation in the central nervous system." Id. She further stated, "[t]he neurotoxicity of aluminum has been well-known since the early 20th century, and the meteoric rise in neurological disorders began shortly after aluminum adjuvant began to be added to pediatric vaccines in 1932." Pet. Ex. 16 at 1. "The bio-persistence of aluminum in the brain leads to an ongoing, permanent immune system activation in some children, which can cause brain inflammation and rapid head growth. Aluminum studies using vaccine adjuvants have shown both behavioral deficits of motor function as well as cognitive deficits." Id.

Dr. Buckley failed to adequately explain how inflammation could cause macrocephaly, or how macrocephaly could lead to developmental delay. Instead, she relied on "well known" evidence associating aluminum with neurological disorders. Dr. Buckley opined J.M.G.'s vaccine caused inflammation, and this led to rapid head growth, but provided little mechanistic theory as to how inflammation catalyzes rapid head growth beyond stating microglial cells in the brain become activated.

No past cases support Dr. Buckley's theory of causation. When hydrocephalus is mentioned in Vaccine Act cases, it often arises in cases involving seizures or autism. See, e.g., Hooker v. Sec'y of Health & Hum. Servs., No. 02-472V, 2016 U.S. Claims LEXIS 825, at *35 (Fed. Cl. Spec. Mstr. May 19, 2016) (noting suspicions of hydrocephalus in an autistic child); Xiangdong He v. Sec'y of Health & Hum. Servs., No. 08-207V, 2012 U.S. Claims LEXIS 2257, at *10-11 (Fed. Cl. Spec. Mstr. Mar. 12, 2012) (noting that an autistic child had also been diagnosed with external hydrocephalus); Nash v. Sec'y of Health & Hum. Servs., No. 00-149V, 2002 U.S. Claims LEXIS 170, at *5 (Fed. Cl. Spec. Mstr. June 27, 2002) (noting that a child with seizures also showed signs of hydrocephalus). To the undersigned's knowledge, the Vaccine Program has not compensated a vaccinee for hydrocephalus or macrocephaly as a principal injury, independent of seizures or another syndrome or disorder. It also has not been compensated for in a case where the claimed injury is autism or developmental delay.

Regarding Dr. Harum, the undersigned notes that Dr. Harum's expert reports in the Program have been found to be unpersuasive, conclusory, and lacking in evidentiary support. See, e.g., Bangerter ex rel. D.B. v. Sec'y of Health & Hum. Servs., No. 15-1186V, 2022 WL 439535, at *34 (Fed. Cl. Spec. Mstr. Jan. 18, 2022); Cakir v. Sec'y of Health & Hum. Servs., No. 15-1474V, 2018 WL 4499835, at *7 (Fed. Cl. Spec. Mstr. July 12, 2018); Ellis v. Sec'y of Health & Hum. Servs., No. 13-336V, 2018 WL 4846547, at *16 (Fed. Cl. Spec. Mstr. Sept. 6, 2018); Pope v. Sec'y of Health & Hum. Servs., No. 14-078V, 2017 WL 2460503, at *20 (Fed. Cl. Spec. Mstr. May 1, 2017); Fester v. Sec'y of Health & Hum. Servs., No. 10-243V, 2016 WL 1745436, at *24 (Fed. Cl. Spec. Mstr. Apr. 7, 2016).

Dr. Harum stated J.M.G. "suffered significant neurological and developmental injury due to the accumulation of spinal fluid and increased intracranial pressures that resulted. The mechanism of injury from increased intracranial pressures is proposed to be ischemic injury to white matter tracts." Pet. Ex. 10 at 2. Although Dr. Harum opined that J.M.G. had increased

intracranial pressures, she did not cite to any of J.M.G.'s medical records to support this opinion. Also, she did not cite to medical records in support of her opinion that J.M.G.'s development delays were caused by increased intracranial pressure.

Dr. Harum next stated that "a small vessel vasculitis/angiitis characterized by macrophage and lymphocyte infiltration likely occurred at the arachnoid villi, thereby impeding [J.M.G.]'s ability to absorb cerebrospinal fluid at the normal rate." Pet. Ex. 10 at 3. This led "to an accumulation of cerebrospinal fluid and neurological impairment via compression of developing cortical neurons." Id. Dr. Harum did not offer evidence to support the claim that J.M.G. suffered from small-vessel vasculitis, angiitis, or ischemic injury to his white matter tracks. No evidence from the medical records or medical literature supports her statements.

Dr. Harum also presented no evidence that vaccines cause hydrocephalus. Nor did she sufficiently explain how hydrocephalus could cause developmental delay. Instead, Dr. Harum cited Marino et al. that documented hydrocephalus is correlated to familial predisposition and is the most frequent cause of macrocephaly. Marino et al. also stated benign external hydrocephalus "can influence psychomotor or motor retardation and behavioural disorders." Pet. Ex. 12 at 3. However, Marino et al. did not reference vaccinations or explain a causative mechanism connecting hydrocephalus and developmental delay.

Accordingly, the undersigned finds petitioner has not offered a sound and reliable medical theory in support of his claim. Thus, petitioner has not met the preponderant evidentiary standard with respect to Althen Prong One.

2. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

Here, a review of the medical records, expert reports, and medical literature do not show

J.M.G. suffered from a vaccine-induced injury. Petitioner filed an expert report and letters from experts, however, these reports, as previously emphasized by the undersigned, do not discuss the Althen Prongs necessary to show causation. Without an expert report providing appropriate evidence of vaccine causation, the undersigned finds that the record does not support a claim under the Vaccine Act, or otherwise include preponderant evidence demonstrating that J.M.G. sustained any vaccine-related injury.

Dr. Buckley asserts the DTaP, and other aluminum-containing vaccines given to J.M.G., "triggered acute brain inflammation, precipitating his rapid head growth and concomitant developmental delay." Medical Records at 2 (ECF No. 10). She opined this was due to the "neurotoxicity of aluminum" adjuvant. Pet. Ex. 16 at 1. However, Dr. Buckley failed to adequately explain how inflammation could cause macrocephaly, or how macrocephaly could lead to developmental delay. Additionally, because Dr. Buckley was not a medical doctor, her assertion that J.M.G.'s physicians had not properly treated him were outside of her specialty. These opinions also diminished the persuasiveness of her report as a whole.

While Dr. Harum accepted the diagnosis of J.M.G.'s treating neurologist, which was benign (or familial) external hydrocephalus, Dr. Harum did not offer evidence to support the claim that J.M.G. suffered from high-pressure communicating hydrocephalus. Dr. Harum stated J.M.G. suffered significant neurological and developmental injury due to the accumulation of spinal fluid and increased intracranial pressures. She stated that the vaccinations J.M.G. received at two months "triggered an inflammatory and oxidizing response in the brain, characterized as Aluminum hydroxide mediated disruption of the blood brain barrier, infiltration of leptomeninx by macrophages and lymphocytes, and perivascular lymphocytic infiltration, damaging brain function at multiple levels [] including arachnoid granulation function." Pet. Ex. 10 at 3. Dr. Harum did not provide any evidence from J.M.G.'s medical records to show J.M.G. suffered from these conditions.

Likewise, Dr. Harum did not offer evidence to support the claim that J.M.G. suffered from small-vessel vasculitis, angiitis, or ischemic injury to his white matter tracks. Dr. Harum stated, "a small vessel vasculitis/angiitis characterized by macrophage and lymphocyte infiltration likely occurred at the arachnoid villi, thereby impeding [J.M.G.]'s ability to absorb cerebrospinal fluid at the normal rate." Pet. Ex. 10 at 3. This led "to an accumulation of cerebrospinal fluid and neurological impairment via compression of developing cortical neurons." Id. Again, Dr. Harum did not cite to the medical records to show J.M.G. suffered from these conditions. Overall, Dr. Harum presented no evidence that vaccines cause hydrocephalus, nor did she sufficiently explain how hydrocephalus could cause developmental delay. As with Dr. Buckley, the undersigned found some of Dr. Harum's opinions conclusory.

Alternatively, the undersigned found respondent's experts persuasive and their opinions supported by medical literature and medical record evidence. First, Dr. Bingham was well-qualified to opine on this topic, and the undersigned found his opinion consistent with that of J.M.G.'s treating neurologist, who diagnosed J.M.G. with benign external hydrocephalus. Dr. Bingham relied on an MRI conducted on May 20, 2015, showing "increased spaces around the brain, but no cerebral abnormalities." Resp. Ex. A at 2. He also noted that the findings of a September 3, 2014 ultrasound were consistent with benign external hydrocephalus. The

undersigned also accepted Dr. Blattman's conclusions.

In reviewing the medical literature filed by the parties, the Marino et al. study, filed by Dr. Harum, supports the conclusion that benign external hydrocephaly is generally "correlated to a familial predisposition and, in some cases, inheritance." Pet. Ex. 12 at 1. The Zahl et al. study, filed by both parties, offered a particularly compelling explanation of the role of heredity in hydrocephalus. See Pet. Ex. 12; Resp. Ex. A, Tab 4. These articles align with Dr. Cokely's opinion that J.M.G.'s condition is probably genetic.

Furthermore, the Yew et al. and Wiig et al. articles filed by respondent discussed complications of external hydrocephalus, but neither observed any association between vaccines and external hydrocephalus. See Resp. Ex. A, Tabs 2-3.

For all of the reasons described above, the undersigned finds that petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect required under Althen Prong Two.

3. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. denied after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

Neither of petitioner's experts opined regarding the onset of J.M.G.'s alleged vaccine-induced injury. Dr. Buckley and Dr. Harum note that J.M.G.'s head circumference accelerated between his two-month and four-month well baby checkups, but did not establish "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. Dr. Harum opines "the etiology of [hydrocephalus] is associated in time and in pathophysiologic mechanisms with his 2 month cluster of vaccines," but she does not provide evidence to support this assertion. Pet. Ex. 10 at 2-3.

Based on a review of all of the evidence, the undersigned finds that petitioner has failed to prove by preponderant evidence of an onset of symptoms occurring in an appropriate time frame after vaccination. Therefore, petitioner has failed to provide preponderant evidence to satisfy Althen Prong Three.

VI. CONCLUSION

It is clear from the medical records that J.M.G. has struggled with illness, and the undersigned has great sympathy for what he and his parents have endured due to his illness. The undersigned's decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

Accordingly, for all the reasons stated above, the undersigned **DENIES** petitioner's motion for recusal and motion to vacate. The undersigned **GRANTS** respondent's motion for order to show cause and to dismiss the case. Additionally, this case is **DISMISSED** for failure to prosecute and for insufficient proof. Moreover, the undersigned finds that petitioner has failed to prove by preponderant evidence that the vaccinations administered to J.M.G. on May 13, 2014 and July 16, 2014 caused any severe adverse reaction. **Thus, entitlement to compensation is denied. The Clerk of Court shall enter judgment accordingly.**

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master